

REMARKS

Status of the Claims

Claim 1 is presently amended. Claims 2-4 and 7-8 are canceled.

Applicants have amended claim 1 to recite the specific definition of the preselected sequence: "nucleic acid comprising the 16S/23S rDNA spacer region". Support for this amendment can be found throughout the specification as filed, for example on page 11 lines 17-29.

Further amendments to claim 1 include incorporation of the "second predetermined cut off value" from previous claim 2. Amended claim 1 now recites a further subclass of data wherein the amount of nucleic acid "is less than said first predetermined cut off value and above said second predetermined cut off value" and "wherein said bacterial pathogen is not confirmed nor excluded if said amount of nucleic acid from said sample comprising the 16S/23S rDNA spacer region is above said second predetermined cut off value but is less than said first predetermined cut off value"; these amendments are supported throughout the specification as filed, for example on page 9 lines 11-17. Additionally, the specific term Polymerase Chain Reaction was incorporated from previous claim 3.

Other minor amendments to claim 1 were made to clarify the claim language and structure. No new matter is added by these amendments.

With entry of these amendments, claims 1 and 5-6 are currently pending and under consideration.

Priority

The Examiner notes that certified copies of foreign priority applications EP 02027272.0 and EP 03007458.7 have not been received by the Office, even though Applicants have provided evidence indicating that the documents were already provided to the Office in the instant application.

Solely to facilitate prosecution and concurrent with the filing of this Response, Applicants again will provide the Office with certified copies of the EP priority documents via US Express Mail mailed concurrently with the filing of this Response.

Information Disclosure Statement

The Examiner asserts that the information disclosure statement filed October 25, 2007, fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the citations are incomplete and complete copies of Humar and Reid references were not received. Applicants regret the inadvertent administrative errors and file herewith via EFS Web a supplemental IDS and form 1449 to correct the citation errors, to provide the complete copies of the missing references, and further to provide additional documents cited in other related pending cases.

Applicants respectfully request consideration of the references, remarks and Information Disclosure Statement filed herewith.

Claim Rejections – 35 USC §102

The Examiner has rejected claims 1-3 and 5-6 under 35 USC 102(e) as being anticipated by Cockerill et al. (Action page 4).

Solely to facilitate prosecution and without acquiescence in the rejections, Applicants have amended claim 1 to recite “nucleic acid ... comprising the 16S/23S rDNA spacer region” (emphasis added). Applicants assert that Cockerill does not teach methods for detecting the presence of a bacterial pathogen by quantifying the amount of nucleic acid comprising the 16S/23S spacer region.

Further, the Examiner asserts in part that Cockerill inherently discloses a second predetermined cut off value (Action page 5). Applicants respectfully traverse this argument. Cockerill does not teach or provide suggestion of a second predetermined cut off value. It is important to note that both the first and second cut off values are predetermined values obtained prior to the analysis of the clinical sample and not simply a measure of an arbitrary determination of “below baseline” as the Examiner suggests (Action page 5). The instant invention requires predetermined values; see for example, see page 9 lines 3-10 of the application as filed:

Predetermination of an appropriate cut off value depends on the mode of quantification that has been chosen and can be done by a person skilled in the art. In this regard, quantitative data obtainable from a large number of clinical samples from patients that have been proven to suffer from a systemic infection of a bacterial pathogen are compared with quantitative data from a large number of samples from individuals that have been proven to be free of any

pathogenic infection. The optimal cut off value is then set in such a way that the numbers of false positive and false negative results are minimized. (emphasis added)

Applicants further direct the Examiner's attention to page 9 lines 11-17 of the application as filed for discussion on the utility and importance of the second predetermined cut off value:

The second class of quantitative data can be subdivided into two subclasses by means of setting a second cut off value. Under these conditions, one class of data remaining under said second cut off value is clearly indicative for the absence of a pathogenic infection, the second class of data exceeding said second cut off value but remaining under said first cut off value represents those cases, where a pathogenic infection is not confirmed but on the other hand can also not be excluded.

Applicants assert that Cockerill does not teach detecting the presence of a bacterial pathogen utilizing a second predetermined cut off value.

The Examiner has not shown that Cockerill teaches each and every limitation of claim 1. Because an asserted §102 reference must contain all limitations of a claim to anticipate that claim, Cockerill cannot be cited as anticipating claim 1 as presently amended. The other rejected claims depend from claim 1 and, therefore, also cannot be rejected based on Cockerill.

For the reasons provided above, Applicants respectfully request reconsideration and withdrawal of the 102(e) rejections.

CONCLUSION

Applicants respectfully request entry of the present RCE and remarks. In view of the above, Applicants believe all claims now pending in this Application are in condition for allowance. If the Examiner believes that a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-730-8566.


Applicants respectfully request a 1-month extension of time to respond to the final Office Action mailed May 1, 2008. The response date was August 1, 2008; with the granting of this request, the response time is re-set to September 1, 2008.

The commissioner is hereby authorized to charge the amount of \$120, the fee due under 37 CFR §1.17(a)(1) and also to charge the amount of \$810, the fee pursuant to 37CFR §1.114, to Deposit Account No. 50-0812. Please grant any additional extensions of time that may be required to enter this amendment and charge any additional fees or credit any overpayments to Deposit Account No. 50-0812.

Please direct all future correspondences to: Customer No. 22829.

Respectfully submitted,

Date: August 28, 2008

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